

1 CLAIMS

2

3 1. A method for producing a vaccine composition
4 containing an immunogenic determinant as the
5 active ingredient, characterised in that the
6 method comprises the steps of:

7 a. treating procaryotic cells under
8 conditions such that an increase of the
9 concentration of trehalose within
10 procaryotic cells is induced;

11 b. using the induced cells containing
12 trehalose as the immunogenic determinant
13 in the production of a vaccine
14 composition.

15

16 2. A method as claimed in claim 1, characterised
17 in that the treatment of the procaryotic cells
18 is carried out to achieve a concentration of
19 trehalose within the cells of at least 10mM.

20

21 3. A method as claimed in either of claims 1 or 2,
22 characterised in that the increase in
23 concentration of trehalose is achieved by
24 synthesis of trehalose within the cell.

25

26 4. A method as claimed in any one of the preceding
27 claims, characterised in that the condition
28 causing the increase of trehalose concentration
29 within the cells is heat, osmotic shock,
30 suppression of degradation of trehalose, or
31 genetically engineered constitutive synthesis
32 of trehalose within the cells.

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- 1 5. A method as claimed in any one of the preceding
2 claims, characterised in that the induced cells
3 containing the trehalose are dried prior to
4 their use in the production of the vaccine
5 composition.
 - 6
 - 7 6. A method as in claim 5, characterised in that
8 the cells are dried in the absence of added
9 extra-cellular carbohydrate glassy stabilising
10 matrix.
 - 11
 - 12 7. A method as claimed in any one of the preceding
13 claims, characterised in that the procaryotic
14 cells are bacteria, protozoa or fungi.
 - 15
 - 16 8. A method as claimed in any one of the preceding
17 claims, characterised in that the procaryotic
18 cells are treated by cultivating them in a
19 medium containing one or more solutes and
20 having an osmolarity of at least 350 mOsmoles.
 - 21
 - 22 9. A method as claimed in claim 8, characterised
23 in that the solute is selected from a sodium,
24 potassium, calcium and / or ammonium salt.
 - 25
 - 26 10. A method as claimed in claim 1, characterised
27 in that the procaryotic cell has been modified
28 so as to synthesise trehalose.
 - 29
 - 30 11. A method as claimed in claim 1, characterised
31 in that the treatment of the cells is carried

- 1 out to achieve a concentration of trehalose
2 within the cells of at least 100mM.
- 3
- 4 12. A method as claimed in any one of the preceding
5 claims, characterised in that the procaryotic
6 cells containing the induced trehalose are
7 killed prior to use in the vaccine composition.
- 8
- 9 13. A method as claimed in any one of the preceding
10 claims, characterised in that the treatment of
11 the procaryotic cells is carried out in vitro.
- 12
- 13 14. A vaccine composition comprising an immunogenic
14 determinant, characterised in that the
15 immunogenic determinant includes a procaryotic
16 cell or cell residue which contains at least
17 10mM of trehalose within the cell.
- 18
- 19 15. A vaccine composition characterised in that it
20 contains an immunogenic determinant produced by
21 the method of any of claims 1 to 13.
- 22
- 23 16. A vaccine composition as claimed in either of
24 claims 14 or 15, characterised in that it
25 contains an adjuvant for the immunogenic
26 determinant.
- 27
- 28 17. A vaccine composition as claimed in any one of
29 claims 14 to 16, characterised in that it
30 contains an aqueous carrier.
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18. A vaccine composition as claimed in any one of claims 14 to 17, characterised in that the induced cells containing trehalose are dried in the presence of a non-reducing carbohydrate to provide a storage stable but viable immunogenic determinant for storage prior to use in a vaccine composition.
19. The use of a composition as claimed in any one of claims 14 to 18 to immunise an animal.
20. A method for treating an animal with a vaccine, characterised in that a pharmaceutically effective amount of a vaccine composition as claimed in any one of claims 14 to 18 is administered to the animal to elicit an immune response in the animal.
21. A method as claimed in claim 20, characterised in that the vaccine composition is administered by injection.
22. A prokaryotic cell which has had its genetic structure modified so as to remove or inhibit that portion of the genetic structure which inhibits or restricts the synthesis of trehalose by the cell whereby the cell constitutively synthesises trehalose within the cell as it grows.